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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	10

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/257,585	Sally A. Leong, et al.
Examiner	**Group Art Unit**
Amy Nelson	1638

X Responsive to communication(s) filed on *Jul 31, 2000* .

This action is **FINAL.**

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) *1-11, 13-17, 25, and 26* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

X Claim(s) *1-11, 13-17, 25, and 26* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

X Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

X Notice of References Cited, PTO-892

X Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I, Claims 1-11, 13-17, 25, and 26, in Paper No. 9, filed 7/31/00, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Applicant has canceled Claims 12, 18-24, and 27-29, drawn to the nonelected inventions, in the response filed 7/31/00. However, part(c) of Claim 11 is directed to nonelected Group II, and hence must be canceled in the next response. Claims 11 and 13-17 are being examined to the extent that they read on an isolated nucleic acid molecule encoding a functional avirulence polypeptide.

Priority

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

> An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-11, 13-17, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn broadly toward an isolated nucleic acid molecule from *Magnaporthe grisea* which confers rice cultivar CO39-specific avirulence to fungal plant pathogens, as well as transformed cells and transgenic plants comprising said nucleic acid molecule. Applicant also claims an isolated nucleic acid molecule comprising at least part of SEQ ID NO:1, which hybridizes with at least part of SEQ ID NO:1, or which encodes at least part of any of SEQ ID NO:2-8. Applicant describes a single nucleic acid molecule isolated from *M. grisea* (SEQ ID NO:1) which confers rice cultivar CO39-specific avirulence to strains of *M. grisea*. Applicant does not describe the composition or structure of other nucleic acid molecules which confer rice cultivar CO39-specific avirulence to fungal plant pathogens, and hence it is not clear from the instant specification that the Applicant was in possession of the invention as broadly claimed

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

6. Claims 1-11, 13-17, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to an isolated nucleic acid molecule encoding SEQ ID NO:4 (ORF 3), as well as transformed host cells and transgenic plants comprising said nucleic acid molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant claims are indefinite for the reasons described below. However, it appears that Applicant intends to claim an isolated nucleic acid molecule from *Magnaporthe grisea* which confers rice cultivar CO39-specific avirulence to fungal plant pathogens, as well as transformed cells and transgenic plants comprising said nucleic acid molecule. Applicant also claims an isolated nucleic acid molecule comprising at least part of SEQ ID NO:1, which hybridizes with at least part of SEQ ID NO:1, or which encodes at least part of any of SEQ ID NO:2-8.

Applicant teaches isolation of a gene from *Magnaporthe grisea* which confers avirulence

teaches by site-directed mutagenesis that ORF1 and ORF 3 of the isolated gene play an active role in conferring avirulence (Example 1). Furthermore, Applicant teaches that in rice plants carrying the resistance gene corresponding to the isolated avirulence gene, treatment with *E. coli* transformed with ORF3 (encoding SEQ ID NO:4) results in reduced lesion size and number upon infection with a virulent strain of *M. grisea* (Example 3). Moreover, treatment of said plants with the recombinantly prepared gene product encoded by ORF3 similarly results in reduced lesion size and number upon infection with a virulent strain of *M. grisea* (Example 4). Applicant does not teach other isolated nucleic acid molecules other than those encoding SEQ ID NO:4 (ORF3) which confer avirulence on rice cultivar CO39. Also, Applicant does not teach transformed cells other than transformed host cells *in vitro*.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The state of the art for isolation of nucleic acid molecules with a defined functionality is highly unpredictable. Significant guidance is required with regard to hybridization/wash conditions and/or PCR conditions that will allow specific isolation of the target genes. Applicant has

avirulence. Applicant has provided no guidance with respect to what hybridization/wash conditions or what PCR reaction conditions would allow specific isolation of additional functionally related genes. In the absence of such guidance, undue trial and error experimentation would be required to screen through the vast number of cDNA and genomic clones from *Magnaporthe grisea*, to identify those that are functionally related to SEQ ID NO:1 and also confer CO39-specific avirulence.

Also, whereas Applicant has specifically taught that ORF3 (which encodes SEQ ID NO:4) is sufficient to confer CO39-specific avirulence, Applicant has provided no guidance for additional parts of SEQ ID NO:1 which confer said avirulence. In the absence of appropriate guidance, undue trial and error experimentation would be required to screen through the myriad of different parts of varied size and region from SEQ ID NO:1, or from another related nucleic acid molecule, to identify those parts which likewise confer CO39-specific avirulence.

Re: Claims 7, 8, and 15. The instant claims read on transformed mammalian cells *in vivo*. Applicant has provided no guidance for transgenic animals, and hence the claims should be limited to transformed host cells (*i.e.* cells *in vitro* or in culture). Also, Applicant has provided no specific guidance for transformed insect or mammalian cells, and it is not clear that the instantly disclosed fungal gene would be properly expressed and processed in an insect or mammalian cell. Therefore, the instant claims should be limited to transformed bacterial, fungal or plant host cells.

When the *Wands* factors are weighed it is concluded that undue experimentation would be required to practice the invention throughout the full scope of the claims, and therefore the invention is not enabled.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2-11, 13-17, 25, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 2, line 2, and Claim 25, line 2, the name "*AVR1-CO39*" is indefinite given that a name does not clearly identify the claimed gene, and does not set forth the metes and bounds of the claimed invention. The sole designation of a gene by its name or number is arbitrary and creates ambiguity in the claims. For example, the gene disclosed in this application could be designated by some other arbitrary means, or the assignment of the name could be arbitrarily changed to designate another gene. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. Since the name *AVR1-CO39* is not known in the art, the use of said name does not carry art recognized limitations as to the specific characteristics or essential characteristics which are associated with that denomination. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970).

At Claim 4, lines 2-3, the phrase "having the features of a polypeptide" is indefinite because polypeptides have many different features, and it is not known what features are intended. Hence, it is not known what is encompassed by the claim. Appropriate correction is required to clarify the metes and bounds of the claimed invention.

Claim 6 is indefinite because a vector is a circular piece of DNA, and hence it is not known how a recombinant DNA can comprise both a vector and another nucleic acid molecule, and how the vector and nucleic acid molecule are attached to one another. Clarification is required.

At Claim 8, "cell" (singular) at line 1 is inconsistent with "cells" (plural) at lines 2-3.

At Claims 9 and 10, "the transformed cell of claim 8" lacks proper antecedent basis.

At Claim 11, part (b) "an allelic variant" does not define "a sequence" as recited at lines 1-2.

At Claim 11, line 10, the phrase "substantially the same as" is indefinite because "substantially" is a relative term and it is not clear how sameness is determined. Hence, it is not known what is encompassed by the claim. Appropriate correction is required to clarify the metes and bounds of the claimed invention.

At Claim 15, "cell" (singular) at line 1 is inconsistent with "cells" (plural) at lines 2-3.

At Claim 25, lines 2-3, the phrase "effective to confer" is indefinite because it is unclear whether or not it confers. The phrase should be changed to --which confers--.

At Claim 26, lines 2-3, the phrase "functional equivalent" is indefinite because it is unclear how equivalence is determined, *i.e.* what characteristic is compared. Also, it is not known if the phrase refers to the bacterium or to ORF3. Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 11, and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimizu *et al.* (Infect. Immun. 59: 137-142, 1991).

The claims are indefinite for the reasons discussed *supra*. In particular, the phrase "substantially the same as" is indefinite. Also, in that "part" is not limited in size and "hybridizing" is not limited in stringency of conditions, the claims read on nearly any isolated nucleic acid molecule.

Shimizu discloses an isolated nucleic acid molecule which has part of SEQ ID NO:1, which hybridizes with part of SEQ ID NO:1, or which encodes part of any of SEQ ID NO:2-8 (Fig. 2). Shimizu also discloses a recombinant DNA comprising said nucleic acid molecule, and an *E. coli* host cell transformed with said nucleic acid molecule (p. 137, right-hand column). Hence,

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the Group receptionist whose telephone number is (703) 308-1234.

Amy Nelson

AMY J. NELSON, PH.D
PRIMARY EXAMINER

Amy J. Nelson, Ph.D.
September 6, 2000